AUG 5 - 2005

K051570 1/1

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: AVL Hinge Knee System

Common Name: Constrained Knee

Classification Name: Knee joint, femorotibial, metal/polymer, constrained, cemented prosthesis (21 CFR 888.3510)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: The AVL Hinge Knee System is substantially equivalent to the following Biomet products: AVL Hinge Knee System (K010774); Orthopedic Salvage System (OSS™) (K002757); Finn® Knee System (K945028).

Device Description: The AVL Hinge Knee System is composed of a modular femoral component that is joined to a modular tibial component by means of a yoke and an axle. A polyethylene bearing lies between the femoral and tibial component. Augments are available for the distal portion of the femoral component.

Intended Use: The indications for use of the AVL Hinge Knee System are:
1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis
2. Correction of varus, valgus or post traumatic deformity
3. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
4. Ligament deficiencies
5. Tumor resections
6. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques
7. Revision of previously failed total joint arthroplasty
8. Trauma

These devices are for cemented use only.

Summary of Technologies: The technological characteristics (materials, design, sizing and indications) of the AVL Hinge Knee System are similar to or identical to the predicate devices or other previously cleared devices.

Clinical and Non-Clinical Testing: None provided

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corporation
56 East Bell Drive.
P.O. Box 587
Warsaw, Indiana 46582

Re: K051570
Trade/Device Name: AVL Hinge Knee System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: June 13, 2005
Received: June 14, 2005

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: AVL Hinge Knee System

Indications For Use:The indications for use of the AVL Hinge Knee System are:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis
2. Correction of varus, valgus or post traumatic deformity
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8. Trauma

These devices are for cemented use only

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K054570